

Remarks/Arguments

The Office Action dated January 9, 2008 has been received and carefully studied.

The applicant wishes to thank the Examiner for her time on April 1, 2008, to discuss the rejection. In accordance with the Examiner's suggestion, the arguments presented during that telephonic interview are repeated in this response. As the Examiner noted, East does not teach a system having two fluid paths, where the flow is directed into one of these two paths in response to the patient's inclination.

The Examiner rejects claims 1-3, 6 and 11 under 35 U.S.C. §102(b) as being anticipated by East et al (U.S. Patent No. 5,167,615). This rejection is respectfully traversed.

With respect to claim 1, the Examiner states that East teaches a system for regulating the flow of cerebrospinal fluid (CSF) from the brain of an individual comprising an implantable controller 10 adapted to be in fluid communication with said CSF and having first and second drainage paths in the form of fluid conduits 36 and 34, respectively, wherein the controller directs the flow of CSF into said first or second drainage path via valves 26 and 28 in response to a change in downstream hydrostatic pressure to a negative downstream hydrostatic pressure, which occurs as a result of a siphoning of said hydrostatic pressure that arises when the user sits, stands or is otherwise held erect i.e. the inclination of said individual. The Examiner cites column 1, lines 51-57, Column 4, lines 60-61 and Column 5, lines 35-44.

This rejection is respectfully traversed. East discloses a system having two fluid paths, however, these paths are not

selected based on the inclination of the individual, as recited in the claim. Referring to the three passages cited by the Examiner, none of these disclose that the selection of a particular fluid path is based on the individual's inclination. The first passage, column 1, lines 51-57, describes the problem caused by the elevation of the inlet with respect to the distal outlet, namely over drainage. It then notes that siphon control devices are used to address this issue. There is no suggestion in this passage that the two fluid paths of East's invention are used to counter the effects of standing or sitting up.

The second passage, column 4, lines 60-61, simply describes the placement of the inlet and outlet catheters. Again, there is no mention of the use of inclination to select a fluid conduit.

The third passage, Column 5, lines 35-44, actually describes how the two fluid conduits are selected. It states that the fluid conduits are "altered by percutaneous manipulation of the device when it is subcutaneously implanted". In other words, the selection of the fluid path is done via intervention outside of the body. Specifically, East discloses that the selection of fluid conduit is done as follows. "A medical professional may ... [adjust the fluid conduit selection] by placing a magnetically polarized ring directly over the flushing reservoir of the device...[T]he polarized ring is simply placed next to the skin and rotated in the direction intended to cause the desired flow rate configuration."" (Column 10, lines 30-39). Claim 1 also confirms that the selection of the fluid conduit is performed by manipulating a polarized ring outside the body. That claim reads, in part, that "the fluid directing means ... [are actuated] by percutaneous manipulation of the device when

subcutaneously implanted". (Claim 1). Thus, East does not disclose that the inclination of the individual plays any role in the selection of the fluid conduit path, as recited in claim 1.

The Examiner rejects claim 2 by noting that the first drainage path taught by East, conduit 36 is a supine flow path in that it is taught by East to be the path of least resistance to fluid flow. The Examiner states that controller 10 directs the flow of said fluid into said supine flow path by occluding the flushable reservoir by positioning plug, thereby permitting flow through second conduit 36, which allow the fluid to bypass the first normally closed valve. The Examiner further asserts that the individual's inclination of supine or substantially supine thereby flows inherently and necessarily from the teachings of East.

This rejection is respectfully traversed. As stated above, the device of East requires a medical professional to manipulate a polarized ring outside the individual's body, directly above the reservoir. Clearly, East does not suggest that this medical professional manipulate the device each time the patient changes his inclination. Therefore, East does not disclose that the lower resistance path is utilized when the patient is in the supine position. Rather, East simply teaches that his device can be easily changed from one threshold to another by a trained medical professional without entering the patient's body to manipulate the magnetic cam. Again, the device cannot select one of the two fluid conduits independent on external manipulation. Thus, claim 2 is not anticipated by this reference.

The Examiner rejects claim 3, stating that second drainage path taught by East is an upright flow path. The Examiner asserts that the limitation "when said individual's

inclination is vertical or substantially vertical" flows necessarily from East's teachings, as the siphon device 30 is activated only in this conduit 34 due to an absence of positive upstream fluid pressure that does occur in conduit 36 because the fluid is permitted to bypass the first valve 26.

This rejection is respectfully traversed. The siphon device 30 of East is located downstream of valves 26 and 28. Thus, it is actually part of both fluid conduits. Figure 4 shows the fluid path when valve 26 is bypassed. Figure 5 shows the fluid path when valve 26 is operational. Note that in both cases, the fluid path includes reservoir 32, through valve 28, intermediate flow channel 62, central SCD reservoir 88, siphon device 30 and outlet flow channel 66. Since siphon device 30 is part of fluid path that is common to both conduits, it cannot perform the function only when the individual sits, stands or is otherwise held erect, as asserted by the Examiner. Furthermore, anti siphon device 30 is active whenever there is positive upstream pressure. This can occur regardless of the individual's inclination. Thus, claim 3 is not anticipated by East.

The Examiner rejects claim 6, using the same argument as presented with respect to claim 2. For the reasons cited above, claim 6 is also not anticipated by East.

The Examiner rejects claim 11, stating that East teaches an inlet connection, an outlet connection spaced from said inlet connection, an inlet cannula and an outlet cannula.

This rejection is respectfully traversed. Since East does not meet the limitations recited in claim 1, it cannot anticipate dependent claim 11.

The Examiner rejects claim 7 under 35 U.S.C. §102(b) as anticipated by, or under 35 U.S.C. §103(a) as obvious over

East et al. The Examiner states that East is presumed to teach a maximum intraventricular pressure, since East discloses all other limitations of the claim.

This rejection is respectfully traversed. Since East does not teach all of the limitations recited in claim 1, it cannot anticipate or make obvious dependent claim 7.

The Examiner rejects claims 4 and 5 under 35 U.S.C. §103(a) as being unpatentable over East in view of Cowan (.S. Patent No. 6,585,677). With respect to claim 4, the Examiner admits that East does not teach an inclination sensor for sensing the inclination of the individual. Cowan teaches a shunt for draining CSF having a valve-gauge comprising an accelerometer as a movement sensor for sensing movement by the patient such as reclining, that would change CSF pressure.

This rejection is respectfully traversed. As described above, East teaches a shunt having 2 fluid conduits, which can only be selected by percutaneous manipulation by a medical profession. Thus, East does not teach or suggest that two different two paths are dynamically selected. Rather, East simply allows the possibility of switching from one path to another, if done by a medical profession. There is no suggestion that having two different fluid conduits in use depending on the patient's inclination would be beneficial. Cowan teaches the use of a sensor as one potential criterion that can be used to "determine when the valve should be opened or closed". Column 5, lines 32-33. Thus, Cowan contemplates having a single fluid path which can be opened or closed based on a number of criteria, one of which is position. Therefore, neither reference teaches or suggests having two different fluid paths, dynamically selectable, based on inclination. In fact, neither teaches or suggests

having two different fluid paths that are dynamically selectable! As stated above, East allows for two conduits, but only one is active until a medical profession manipulates the device. There is no way for the device of East to dynamically select between these paths. Gowan does not teach two fluid conduits. Furthermore, the device of East can only be manipulated externally by a medical profession. To apply the position sensor of Gowan to such a device would be impractical. It is submitted that to combine these references to find the present invention obvious requires impermissible hindsight.

The Examiner rejects claim 5, noting that East teaches a bi-stable latching valve in the form of plug 104.

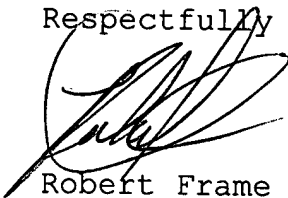
This rejection is respectfully traversed. This claim requires that the bistable latching valve be controlled by a controller. In the device of East, the selection between the first and second fluid conduits is performed manually by a medical profession. There is no controller which controls plug 104. Thus, the limitations of this claim are not met by East. Furthermore, since the limitations of claim 4 are not met by the combination of East and Gowan, claim 5, which is dependent on claim 4, cannot be obvious.

The Examiner rejects claims 8-10 under 35 U.S.C. §103(a) as being unpatentable over East et al in view of Hakim (U.S. Patent No. 3,886,948). The Examiner states that East teaches an anti-siphon device that is considered to function as a check valve. The Examiner states that Hakim teaches a ventricular shunt having a variable pressure valve. The Examiner then asserts that it would be obvious to modify the device of East such that the check valve in the form of anti-siphon device 30 is programmable as taught by Hakim.

This rejection is respectfully traversed. According to East, "an exemplary siphon control device is found in U.S. Patent No. 4,795,437." Column 1, lines 62-63. This patent describes an anti-siphon device, similar to that pictured in East. The device has an upper and lower diaphragm, which can expand to allow fluid movement in the presence of positive pressure. However, in the presence of negative downstream pressure, the diaphragms do not expand, thereby inhibiting a siphoning effect. This device is simply a specific configuration of plastic parts. There is no mechanism by which this device can be made programmable, as there are no programmable parts. Furthermore, the device of Hakim shows a spherical member in all embodiments. Such a member does not exist in the device of East. Therefore, it is not obvious as to how one would combine these teaching to create the required programmable check valve, without the use of impermissible hindsight. Furthermore, since East does not anticipate claim 1, and Hakim does not disclose the missing elements, this dependent claim cannot be made obvious by that combination of references.

Reconsideration and allowance are respectfully requested in view of the foregoing.

Respectfully submitted,



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